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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/773,596 02/06/2004 Alexander K. Mills WT-02-004DIV2 7590 12/10/2004 **EXAMINER** FRANCIS LAW GROUP MALLARI, PATRICIA C 1942 EMBARCADERE OAKLAND, CA 94606, CA 94606 ART UNIT PAPER NUMBER

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/773,596	MILLS, ALEXANDER K.
	Examiner	Art Unit
	Patricia C. Mallari	3736
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1)⊠ Responsive to communication(s) filed on <u>06 February 2004</u> .		
2a) This action is <b>FINAL</b> . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>13,19,26 and 27</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5)⊠ Claim(s) <u>13 and 19</u> is/are allowed.		
6)⊠ Claim(s) <u>26.27</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)⊠ The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>06 February 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)	□	(070, 110)
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da	
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		atent Application (PTO-152)

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### **Priority**

The applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. It is noted that prior Application No. 09/684,104, now US Patent No. 6,537,225, was issued on 3/23/03, but the filing date of the present application was 2/6/04.

This application discloses and claims only subject matter disclosed in prior Application No. 10/196,474, now US Patent No. 6,719,705, filed 7/15/02, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

#### Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

The specification fails to provide adequate support or antecedent basis for a method wherein central venous drainage is determined from a rate of change of absorbance values comprising the step of computing a blood parameter at a first probe position based on the first probe position absorbance, as claimed. A method is

disclosed wherein a blood parameter at a first probe position is computed based on the first probe position absorbance (paragraph 00125 of the instant specification), but that method fails to also include determination of central venous drainage.

The specification further lacks antecedent basis for such a method comprising a step of moving the extremity to a plurality of extremity positions relative to the first probe position. The specification describes such a method wherein the extremity bearing a second probe is moved to a plurality of extremity positions relative to the location of a first probe (paragraph 00126 of the instant specification), but fails to describe such a method wherein the extremity bearing a first probe is moved to a plurality of positions relative the initial position of the extremity, as claimed.

Finally, the specification lacks antecedent basis for such a method wherein the rate of change of absorbance at each of the plurality of extremity positions is compared with the first probe position absorbance to determine a plurality of rate of change absorbance values.

#### Claim Objections

Claim 26 is objected to because of the following informalities: on line 23 of the claim "said second passage" should be replaced with "said second radiation after passage". Appropriate correction is required.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,537,225 to Mills

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Mills teaches a method for noninvasively determining a physiological characteristic of a patient's blood wherein a first tissue probe, having a first radiation emitter and a first radiation detector, is provided, the detector being adapted to received radiation having a first wavelength emitted from the first emitter after absorbance through the patient's blood (figs. 2, 5, 8; col. 8, lines 13-47 of Mills). A second tissue probe, having a second emitter and radiation detector, is provided, the second detector adapted to receive second radiation emitted by the second emitter having a second wavelength after absorbance through the patient's blood. The first tissue probe is placed proximate the first extremity of the patient. The second probe is placed proximate a second, opposing extremity of the patient. The first extremity is placed at a first position whereby the first probe is positioned at a level corresponding to the

patient's heart. The second extremity is placed at a second extremity initial positioned whereby the second probe is positioned below the first probe (col. 16, lines 7-24 of Mills). The second extremity is raised to a plurality of second extremity levels. The absorbance of the patient's blood in the first extremity is measured by detecting the first radiation emitted by the first emitter after passage through the blood. The absorbance is measured substantially continuously in the second extremity during the raising of the second extremity by detecting the second radiation emitted by the second emitter after passage through the blood (col. 16, lines 25-29 of Mills). The rate of change of the absorbance of the second extremity is determined at each of the extremity levels relative to the first extremity absorbance to determine a plurality of rates of change of absorbance values. Central venous drainage is determined form the rate of change of absorbance values (col. 16, lines 29-33 of Mills).

Regarding claim 27, the hydrostatic pressure difference between the position of the second tissue probe corresponding to the central venous drainage and the first probe position is determined and the central venous pressure is calculated form the hydrostatic pressure difference (col. 16, lines 32-37 of Mills).

#### Allowable Subject Matter

Claims 13 and 19 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 13 and 19, the prior art of record fails to teach or fairly suggest a method wherein central venous drainage is determined from a rate of change of

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absorbance values at each of a plurality of extremity positions to which an extremity, on which a probe is placed, is moved, comprising any of the steps of computing a blood parameter at the first probe location based on the first probe position absorbance, moving the extremity to a plurality of extremity positions relative to the first probe location, or comparing the rate of change of absorbance at each of the plurality of extremity positions with the first probe position absorbance to determine a plurality of rate of change of absorbance values, as claimed.

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 6,120,459 to Nitzan et al.

US Patent No. 6,322,515 to Goor et al.

US Patent No. 5,978,691 to Mills

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari Patent Examiner Art Uni 3736

> ROBERT L. NASSER PRIMARY EXAMINER

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